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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BERTOGLIO, VALARIE E

ART UNIT

PAPER NUMBER

1632

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/533,781	Applicant(s) BARSOVA ET AL.	
	Examiner Valarie Bertoglio	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 10 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 19-27 is/are pending in the application.
- 4a) Of the above claim(s) 9-11, 14-16 and 19-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 12-13, 17, 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 February 2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's reply filed on 02/10/2009 is acknowledged. Claims 1,6-7 are amended. Claim 18 is cancelled.

Claims 9-11,14-16,19-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 06/25/2008.

Claims 1-17,19-27 are pending. Claims 9-11,14-16,19-26 are withdrawn. Claims 1-8,12-13,17 and 27 are under consideration in the instant office action.

This application contains claims 9-11,14-16,19-26 drawn to an invention nonelected with traverse in the reply filed on 06/25/2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. **The new sequence listing submitted 02/10/2009 lack the required statement of identity and CRF.** Applicants must file a "Sequence Listing" accompanied by directions to enter the listing into the specification as an amendment. Applicant also must provide statements regarding sameness and new matter with regards to the CRF and the "Sequence Listing."

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer, from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply. Failure to fully comply with the sequence rules in response to the instant office action will be considered non-responsive.

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Specification

The objection to the specification is withdrawn in light of Applicant's amendment.

Claim Rejections - 35 USC § 112-1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 1-8,12-13,17 and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule selected from the group consisting of a) a nucleic acid that encodes a protein comprising the amino acid sequence as shown in SEQ ID NOs: 4,18,20,22,24,26, or 28 and cells and vectors comprising said nucleic acid, does not reasonably provide enablement for other claimed embodiments embraced by the breadth of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The rejection is maintained for reasons of record set forth at pages 3-7 of the office action dated 10/10/2009.

The claims encompass nucleic acids encoding ppluGFP2 and a number of variants that encode mutated forms of ppluGFP2 with various beneficial characteristics. The specification teaches a number of variants that are mutated at specific residues to optimize the encoded proteins. The specification teaches using mammalian-optimized codons as well as yeast-optimized codons (page 22) and used random mutagenesis to generate a cyan emitting protein as well as alter maturation speed and brightness. The specification also teaches a variant that has a lesser tendency to form aggregates. However, the

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specification does not teach the broad genus of fragments and nucleic acids that hybridize to either the claimed full length sequences or fragments.

The aspect of the rejection relating to nucleic acids that hybridize is withdrawn in light of Applicant's amendment to claim 1. This limitation has been removed from the claim.

The claims encompass nucleic acids encoding fragments of SEQ ID NO: 2,4,6,8,10,12,14,16,18,20,22,24,26 and 28 as well as variants having 80% identity to said SEQ IDs. The level of experimentation to determine which of the fragments or protein variants would encode or have the desired and useful activity would be undue. Applicant has amended claim 1 such that it no longer is drawn to nucleic acid fragments. However, claim 12 is drawn specifically to a fragment of the nucleic acid of claim 1 that encodes any peptide of at least 100 amino acids in length. The functional domains necessary and sufficient for the luminescent activity is not disclosed, an artisan would not know which sequences would need to be conserved to render the equivalent biological function as claimed. The skilled artisan would not know which sequences would need to be conserved to render the equivalent biological to the claimed SEQ ID NOs such that one of skill in the art would know how to use them. An artisan would not know which fragments or which 20% of the sequence could be altered and still retain function. One skilled in the art would have to make and test with further experimentation an enormous number of nucleic acids that meet the structural limitations and determine how to use them.

Applicant argues that it would not require an undue amount of experimentation to determine which nucleic acids encoding a protein with 80% homology to the recited SEQ IDs have maintained a fluorescent property. In response, a requirement for exhibiting a fluorescent property is not recited in the body of the claims and it is not clear exactly what a 'fluorescent property' would encompass. The claims encompass any and all nucleic acids that meet the structural limitation of the claims. One of skill in the art would not know how to use all of these nucleic acids.

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Applicant argues that the functional domain necessary and sufficient for the fluorescent activity of GFP-like proteins is well known in the art and can be detected using BLAST software (see Remarks at page 13). In response, further experimentation is necessary to correlate the structure with the function. Experimentation that requires routine repetition to find something that is already known to exist is not undue. However, experimentation to acquire new knowledge (i.e map out functional domains of a protein) is undue as the invention must be in Applicant's possession and enablement is determined as of the effective filing date of the application.

Claim 7 has been amended to recite "a isolated cell". Thus the aspect of the rejection regarding cells in vivo is withdrawn.

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1-8,12-13,17-18 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 1,5,6,7,8,17,27 under 35 U.S.C. 102(b) as being anticipated by Pekarsky (1998, PNAS, 95:8744-8749) as evidenced by GenBank AF069958 is withdrawn in light of Applicant's amendments to the claims.

The rejection of claims 1,5,6,7,8,17,27 under 35 U.S.C. 102(a) and (e) as being anticipated by US 7157566 (filed April 2002; published March 2003) is withdrawn in light of Applicant's amendments to the claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Valarie Bertoglio/
Primary Examiner
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